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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,374

07/14/2006

Robert G.K. Donald

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/586,374	DONALD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-19 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-19 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0706</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicants' election, without traverse, of Invention I(A) in their response of December 12, 2008 is acknowledged. The elected invention is directed to polynucleotides encoding the casein kinase I (CKI) polypeptide of SEQ ID NO: 2. It is acknowledged that with Applicants' response, Claims 4-6, 26, 27, 31, 32, and 35-37 are cancelled, Claims 12, 13, and 16 are amended, and Claim 38 is added. Claims 12-19 and 38 are pending and, as encompassed by the elected invention, are hereby examined.

#### ***Priority***

The priority date granted for the instant invention is January 16, 2004, the filing date of US 60/537,094, which disclosed the elected invention.

#### ***Title***

The title is objected to because it is not descriptive of the elected invention, which is a polynucleotide.

#### ***Specification-Objections***

Applicants are requested to confirm that the specification, file-date of June 6, 2008, and annotated WO/2005/070180 and PCT/US2005/000955, is the currently pending specification. For purposes of examination, it is assumed that said specification dated June 6, 2008 is the currently pending specification. Confirmation and/or explanation is requested.

The first paragraph of the specification should be updated to reflect the current status of all parent applications.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e., via an issued patent, to refer to any commercial sites, since the USPTO exercises

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no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-19 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 12, the phrase “moderate to high stringency” renders the claim indefinite, as this phrase is unclear absent a statement of the conditions under which the hybridization reaction is preformed. Nucleic acids that will hybridize under some hybridization conditions, will not necessarily hybridize under different conditions. The description of hybridization conditions on pages 26-27 are only exemplary and do not define the metes and bounds of the current claims.

Claims 13-15 and 38, as dependent on Claim 12, are indefinite for the same reason.

For Claim 12, lines 4-5 & 7-8, Claim 12, lines 2-3, Claim 16, lines 2-3, Claim 17, lines 2-3, and Claim 38, line 2, the phrases “an amino acid sequence as set forth in SEQ ID NO: 2”, “an amino acid sequence of SEQ ID NO: 2” and/or “a nucleic acid sequence of SEQ ID NO: 1” renders the claims indefinite. It is unclear whether said phrases mean “the sequence of SEQ ID NO: ...” or “any sequence of SEQ ID NO: ...”. The latter would encompass sequences as small as dipeptides and six nucleotides. The skilled artisan would not know the metes and bounds of

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the recited invention. Claims 13-15, 18, 19 and 38, as dependent from Claim 12, 16, 17 and/or 38, are indefinite for the same reason. For purposes of examination, it is assumed that said phrases mean “the sequence of SEQ ID NO: ...”.

For Claim 38, the phrase “encodes an[the] amino acid sequence as set forth by SEQ ID NO: 2” renders the claim indefinite. It is unclear whether said phrase means “encodes a polypeptide comprising the amino acid sequence as set forth by SEQ ID NO: 2” or “encodes a polypeptide consisting of the amino acid sequence as set forth by SEQ ID NO: 2”. The skilled artisan would not know the metes and bounds of the recited invention. Claims 13-15, as dependent from Claim 38, are indefinite for the same reason. For purposes of examination, it is assumed that said phrase means “encodes a polypeptide comprising the amino acid sequence as set forth by SEQ ID NO: 2”.

Claims 13-15 and 17-19 are rendered indefinite for improper antecedent usage as follows.

For Claims 13 and 17, the phrase “a nucleic acid molecule of claim...” should be corrected to “the nucleic acid molecule of claim...”. Claims 14, 15, 18, and 19, as dependent from Claim 13 or 17, are indefinite for the same reasons.

For Claims 15 and 19, the phrase “the host cells of step (a)” should be corrected to “the host cell of step (a)”.

### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### **Enablement**

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide encoding any CKI protein having at least 80% identity to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claim 12 is so broad as to encompass any polynucleotide encoding a protein having at least 80% activity with SEQ ID NO: 2 and having any CKI “multipotential serine/threonine protein kinase activity” (PGPub[0058]). The scope of this claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein

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determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired multipotential serine/threonine protein kinase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 2 and the nucleotide sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Moreover, the specification fails to provide methods for assessing all CKI "multipotential serine/threonine protein kinase activity(s)". In addition, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claim 12, which encompasses all polynucleotide sequences that encode any protein having at least 80% activity with SEQ ID NO: 2 and having "multipotential serine/threonine protein kinase activity". The specification does not support the broad scope of Claim 1 because the specification does not establish: (A) the desired specific and substantial activity for all proteins having at least 80% activity with SEQ ID NO: 2;

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(B) regions of the protein structure which may be modified without affecting the desired activity; (C) the general tolerance of the desired activity to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotides encoding any polypeptide with an enormous number of amino acid modifications of the polypeptide of SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### **Written Description**

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules having the limitations of encoding a protein having at least 80% identity with SEQ ID NO:2 and having any CKI activity. The specification does not contain any disclosure of the desired function of all said DNA sequences or the encoded polypeptides. The genus of polynucleotides that comprise



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these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally distinct DNAs are encompassed within the scope of these claims. The specification discloses the function of only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Allowable Subject Matter***

No claims are allowable.

**Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652